NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

SMITHKLINE BEECHAM CORP., d/b/a GLAXOSMITHKLINE,	:	
Plaintiff,	:	CIVIL ACTION NO. 03-2158 (MLC)
v.	:	**MEMORANDUM OPINION**
RANBAXY LABORATORIES, LTD. and RANBAXY PHARMACEUTICALS, INC.,	:	
Defendants.	:	

COOPER, District Judge

Plaintiff Smithkline Beecham Corp. d/b/a GlaxoSmithKline ("GSK"), holds U.S. Patent No. 4,957,924 ("the '924 patent"), which claims, inter alia, the compound valacyclovir hydrochloride ("valacyclovir" or "the compound"). The complaint charges defendants Ranbaxy Laboratories, Ltd. and Ranbaxy Pharmaceuticals, Inc. (collectively, "Ranbaxy") with infringing the '924 patent. Pending before the Court are cross-motions for partial summary judgment pursuant to Federal Rule of Civil Procedure 56. In its motion for partial summary judgment, Ranbaxy contends that certain claims of the '924 patent are invalid under 35 U.S.C. § 102(b) because the claimed invention was in public use more than one year before the patent application was filed. GSK's cross-motion asserts no patent invalidity due to public use. For the reasons stated herein, the evidence establishes that, as a matter of law, the invention was

not in public use more than one year prior to GSK filing the patent application. Accordingly, we will grant GSK's cross-motion and deny Ranbaxy's motion.

BACKGROUND

The following facts are undisputed. Additional facts relevant to the disposition of these cross-motions will be presented in conjunction with the discussion of the pertinent legal argument.

Scientists at GSK, in the early 1970's, discovered the compound acyclovir, which is used to treat various herpes indications.[1] (Rienzi Cert., Ex. A, Darby, Acyclovir and Beyond, at 33A-34A.) Acyclovir, although safe, had limited oral bioavailability and thus had to be administered in large doses and/or with great frequency to achieve clinical effectiveness.[2] (GSK Fact Statement at ¶¶ 2, 3; GSK Br. at 3.) GSK thus endeavored to create a more bioavailable version of acyclovir. (GSK Fact Statement at ¶ 4.)

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[1] At the time the relevant events occurred, the inventor and others involved in the development and testing of valacyclovir hydrochloride and other amino acid ester prodrugs of acyclovir were employed by Burroughs Wellcome, a predecessor organization to GSK. For ease of reference, we use "GSK" to denote plaintiff and its various predecessor organizations.

[2] Oral bioavailability refers to the percentage of a compound that reaches the bloodstream following oral administration.

Lilia Beauchamp, a chemist in GSK's Organic Chemistry Department from 1957 to 1995, undertook to discover a more bioavailable version of acyclovir by synthesizing a series of amino acid esters of acyclovir. (Id. at ¶¶ 4, 6.) On February 24, 1987, she synthesized the chemical compound valacyclovir hydrochloride--an amino acid ester derivative of acyclovir. (Ranbaxy Fact Statement at ¶ 2.) Ms. Beauchamp provided samples to Drs. Thomas Krenitsky and Paulo de Miranda, senior scientists in GSK's Experimental Therapy Department, to obtain oral bioavailability data on the various compounds she developed, including valacyclovir.[3] (GSK Fact Statement at ¶¶ 5, 7, 8, 11.) Dr. de Miranda and his assistant, Thymista Burnette, conducted an oral bioavailability assay involving urinary recovery testing in rats. (Id. at ¶ 10.) Ms. Beauchamp, an organic chemist, did not perform any bioavailability testing herself. She relied instead on the expertise of and the data provided by Dr. de Miranda and his assistant to guide her creation of additional compounds. (Ranbaxy Response to GSK Fact Statement ("Ranbaxy Fact Response") at ¶ 9.)

Dr. de Miranda, along with Dr. Krenitsky and Dr. Don Nelson, another senior scientist in GSK's Experimental Therapy Department, in addition to conducting the rat bioavailability

[3] Dr. Paulo de Miranda is deceased. He was not deposed in this litigation.

assays, self-administered single doses of valacyclovir and other amino acid esters of acyclovir prepared by Ms. Beauchamp. (GSK Fact Statement at ¶ 11; Ranbaxy Fact Response at ¶ 11.) The purpose of self-ingesting the compounds was to collect human bioavailability data and evaluate which compound possessed optimum bioavailability vis-a-vis the other synthesized compounds. (Id. at ¶¶ 11, 15.) Dr. Krenitsky ingested valacyclovir on March 16, 1987, and again on August 3, 1987. (Ranbaxy Fact Statement at ¶ 3.) Drs. de Miranda and Nelson each self-administered the compound on March 31, 1987. (Id.) Each scientist consumed a valacyclovir capsule in the morning on-site at GSK, and collected urine samples for a twelve to twenty-four hour period thereafter. (GSK Fact Statement at ¶ 12.) None harbored safety concerns about ingesting the compound because it was expected that the body would convert valacyclovir into acyclovir and L-valine, which is a naturally-occurring amino acid. (Id. at ¶ 17; Ranbaxy Fact Response at ¶ 17.) Ms. Burnette analyzed the urine samples collected from the scientists using a protocol similar to that employed in analyzing the rat urine samples. (GSK Fact Statement at ¶ 13.) Although Ms. Beauchamp did not dictate the specific methods of the Experimental Therapy Department's bioavailability testing, she was informed of and did rely upon both the human and rat bioavailability test results. (Id. at ¶ 20.)

The patent in suit is U.S. Patent No. 4,957,924. (Ranbaxy Fact Statement at ¶ 1.) The patent lists Lilia Beauchamp as the inventor and GSK as the assignee. (Krzeminski Decl., Ex. E, U.S. Patent No. 4,957,924 ("the '924 patent").) Claims 1-3, 17, and 22 of the '924 patent cover the compound valacyclovir hydrochloride per se, and include no further limitations to the use or formulation of the compound. (Id. at col. 13:54-61; col. 14:43-44; col. 14:56-57.) Ranbaxy contends that because Drs. Krenitsky, Nelson and de Miranda consumed valacyclovir prior to the critical date, the aforementioned claims are invalid pursuant to the public use bar of 35 U.S.C. § 102(b). (See Ranbaxy Br. at 1-2.) GSK filed the application for the '924 patent on August 4, 1998, and does not dispute that the challenged uses occurred before August 4, 1997. (See the '924 patent; GSK Fact Response at ¶ 3.) Accordingly, we need only decide whether the doctors' self-administrations constituted "public uses" within the meaning of 35 U.S.C. § 102(b).

DISCUSSION

I. Standard and Burden of Proof

Federal Rule of Civil Procedure 56(c) provides that summary judgment is proper "if the pleadings, depositions, answers to interrogatories and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment

as a matter of law." Fed. R. Civ. P. 56(c). The party moving for summary judgment bears the initial burden of showing that there is no genuine issue of material fact. Celotex Corp. v. Catrett, 477 U.S. 317, 323 (1986). Once the moving party has met its initial burden, the non-moving party must present evidence that establishes that a genuine issue of material fact exists, making it necessary to resolve the difference at trial. Id. at 324. A non-moving party may not rely on mere allegations; it must present actual evidence that creates a genuine issue of material fact. Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 249 (1986).

In deciding a motion for summary judgment, the Court must view the evidence in the light most favorable to the non-moving party. Matsushita Elec. Indus. Co. v. Zenith Radio Corp., 475 U.S. 574, 587 (1986). The role of the Court at the summary judgment stage is not to weigh the evidence, but to determine whether there is a genuine issue for trial. Anderson, 477 U.S. at 249. "By its very terms, the standard provides that the mere existence of some alleged factual dispute between the parties will not defeat an otherwise properly supported motion for summary judgment; the requirement is that there be no genuine issue of material fact." Id. at 247-48 (emphasis in original). Material facts are only those facts that might affect the outcome of the action under governing law. Id. at 248. "[T]here is no

issue for trial unless there is sufficient evidence favoring the nonmoving party for a jury to return a verdict for that party. If the evidence is merely colorable or is not significantly probative, summary judgment may be granted." Id. at 249-50 (citation omitted).

The cross-motions for partial summary judgment currently before the Court focus upon whether the public use bar of 35 U.S.C. § 102(b) renders invalid specific claims of the '924 patent. Whether a patent is invalid for a public use is a question of law based on underlying facts, and thus may be ripe for resolution on summary judgment. Netscape Communs. Corp. v. Konrad, 295 F.3d 1315, 1320 (Fed. Cir. 2002). 35 U.S.C. § 282, which attaches a presumption of validity to each patent, places the burden of establishing the invalidity of a patent or claim upon the party asserting such invalidity. 35 U.S.C. § 282. The party asserting the invalidity of a patent or claim based on public use must prove public use by clear and convincing evidence. Id.; Netscape, 295 F.3d at 1320. While the burden of production may shift in the course of summary judgment, the burden of persuasion rests permanently with the challenger. TP Labs., Inc. v. Prof'l Positioners, Inc., 724 F.2d 965, 971 (Fed. Cir. 1984). Accordingly, Ranbaxy bears the burden of proving invalidity under 35 U.S.C. § 102(b) by clear and convincing evidence throughout the entirety of this action.

II. Public Use

An inventor "shall be entitled to a patent unless . . . the invention was in public use . . . in this country, more than one year prior to the date of the application for patent in the United States." 35 U.S.C. § 102(b) (2004). The Federal Circuit has repeatedly defined "public use" as involving "any use of [the claimed] invention by a person other than the inventor who is under no limitation, restriction or obligation of secrecy to the inventor." Netscape, 295 F.3d at 1320 (quotations and citations omitted). This statutory bar promotes the following policies of the patent system:

> (1) discouraging the removal, from the public domain, of inventions that the public reasonably has come to believe are freely available; (2) favoring the prompt and widespread disclosure of inventions; (3) allowing the inventor a reasonable amount of time following sales activity to determine the potential economic value of a patent; and (4) prohibiting the inventor from commercially exploiting the invention for a period greater than the statutorily prescribed time.

Baxter Int'l, Inc. v. COBE Labs., Inc., 88 F.3d 1054, 1058 (Fed. Cir. 1996) (quotations omitted).

The law recognizes, however, that the inventor may require a period of evaluation to ascertain whether the invention will serve its intended purpose. New Railhead Mfg., L.L.C. v. Vermeer Mfg. Co., 298 F.3d 1290, 1297 (Fed. Cir. 2002). What may otherwise appear to be public use, therefore, is negated if the inventor was testing claimed features of the invention.

Smithkline Beecham Corp. v. Apotex Corp., 365 F.3d 1306, 1317 (Fed. Cir. 2004). Once a challenging party has proven by clear and convincing evidence that the invention was in public use before the critical date, the patentee must come forward with evidence sufficient to create a genuine issue of material fact that the use qualified as experimental. Lough v. Brunswick Corp., 86 F.3d 1113, 1120 (Fed. Cir. 1996). Because the experimental use doctrine operates as a negation--and not an exception--to public use, however, the ultimate burden of proving by clear and convincing evidence that the non-experimental use was public under § 102(b) remains with the challenger. Apotex, 365 F.3d at 1317.

"[T]he public use bar of § 102(b) requires that (1) the invention was used in public and (2) the use was not primarily experimental in purpose." Allied Colloids Inc. v. Am. Cyanamid Co., 64 F.3d 1570, 1574 (Fed. Cir. 1995). To determine whether a public use has occurred within the meaning of § 102(b), the Court must examine the totality of the circumstances in light of the policies underlying the public use bar. Netscape, 295 F.3d at 1320. The circumstances may include, but are not limited to,

> the nature of the activity that occurred in public; the public access to and knowledge of the public use; whether there was any confidentiality obligation imposed on persons who observed the use; whether persons other than the inventor performed the testing; the number of tests; the length of the test period in relation to tests of similar devices; and whether the inventor received payment for the testing.

Id. (citations omitted). The Court may take additional factors into account if pertinent to the public nature of the use or any asserted experimental purpose. Id. All of the circumstances must be considered, and no single factor is dispositive. Allied Colloids, 64 F.3d at 1574.

Applying these factors against the backdrop of the policies underlying the public use bar compels the conclusion here that the human uses of valacyclovir did not constitute public uses within the meaning of 35 U.S.C. § 102(b). We now turn to examining each of the relevant factors.

A. Evaluation of the totality of the circumstances

1. The nature of the activity that occurred in public

The activity in issue involved the ingestion of valacyclovir by three senior scientists of GSK's Experimental Therapy Department to assess the compound's oral bioavailability in humans. (GSK Fact Statement at ¶¶ 11, 15; Ranbaxy Fact Response at ¶¶ 11, 15.) The inventor, Ms. Beauchamp, furnished samples of valacyclovir to Dr. de Miranda, a Group Leader of the Experimental Therapy Department, for the sole purpose of procuring oral bioavailability data. (GSK Fact Statement at ¶¶ 5, 7, 8.) Although Ms. Beauchamp was not aware that the Experimental Therapy Department scientists obtained human bioavailability results on valacyclovir until after she received those results, she testified that both the human and rat data

were important to her. (Krzeminski Decl., Ex. A, 8-14-04 and 8-29-04 Dep. of Ms. Lilia Beauchamp ("Beauchamp Dep.") at 227-30, 238-39.)

The scientists' purpose for consuming valacyclovir is not in dispute. GSK's development program to obtain a more bioavailable version of acyclovir included securing human bioavailability data on valacyclovir. (GSK Fact Statement at ¶ 11; Ranbaxy Fact Response at ¶ 11.) Dr. Krenitsky testified that he decided to ingest the whole series of amino acid esters produced by Ms. Beauchamp so that the rat and human oral bioavailability data could be compared. (Id. at ¶ 15.) Dr. Nelson consumed valacyclovir because "[t]hese sorts of studies were part of our experimental strategy to understand the bioavailability and metabolism of interesting candidates." (Krzeminski Decl., Ex. H, Dep. of Dr. Donald Nelson taken on 6-24-04 ("Nelson Dep.") at 14-15.)

The scientists' ingestion of valacyclovir did not occur in public. Rather, the ingestion was part of GSK's intra-company testing. Three GSK senior scientists self-administered the compound at GSK's premises. (GSK Fact Statement at ¶ 12.) The urinary assays were conducted at GSK as well. (Id. at ¶ 13.)

The inventor's directive that oral bioavailability testing be conducted on valacyclovir, her later-acquired knowledge and reliance on the human bioavailability results, and the non-public

situs of the testing are undisputed facts that militate in favor of a determination of nonpublic use. Cf. Allied Colloids, Inc. v. Am. Cyanamid Co., 64 F.3d 1570, 1575-76 (supporting holding that reasonable jury could find no public use with fact that testing at customer's facility was not observed or conducted by anyone other than patent owner's employees).

2. The public access to and knowledge of the public use

Ranbaxy has not raised any genuine dispute that persons outside of GSK had knowledge of valacyclovir or the rat or human bioavailability data prior to the critical date. Specifically, Ranbaxy's assertion that "Krenitsky even went so far as to say that he probably told people outside of GSK that he was taking the compound" is based on its misleading citation of Dr. Krenitsky's deposition testimony. (Ranbaxy Reply Br. at 9.) Dr. Krenitsky testified as follows:

> Q: Who is it -- did you tell anyone that you were ingesting drugs under development?
> (Objection.)
> A: There were people that knew.
> Q: Anyone outside of Burroughs Wellcome?
> A: Probably. I can't remember specifically. I may have told friends.
> Q: Okay. That's the reason why I was asking if you were living with someone.
> A: Yeah. I mean, if I go out to dinner and had a bottle, you know, paper bag with a bottle of urine in it, you know, carrying the paper bag to the men's room, I mean, it was only polite to explain what was going on to people. But--

(Krzeminski Decl., Ex. J, Dep. of Thomas Krenitsky taken on 4-28-04 ("Krenitsky Dep. I") at 132.) Upon being further questioned

about the matter in his second deposition, however, Dr. Krenitsky provided the following clarifications:

> Q: And so just to clarify, you may have told other people that you were taking prodrugs of acyclovir but you may not have told them specifically it was valacyclovir?
> (Objection.)
> A: Not "may not." I definitely did not tell them anything specifically. I tried to explain in this deposition that we were taking urine samples, 24-hour at times, 24-hour urine samples so I take the capsule in the morning and I take the -- . . . . And I would have to carry that bottle around with me. . . . And I felt I had to tell my colleagues why I'm doing this kind of unusual thing. And I say, well, we're doing an experiment . . . you know, that's involved with science and experiment. But I certainly would never say I am taking the L-valyl ester of acyclovir.
> . . . .
> I would say, I'm doing an experiment, I have to take a urine sample. That was the extent of it. Nothing more specific.

(Krzeminski Decl., Ex. I, Dep. of Thomas Krenitsky taken on 6-24-04 ("Krenitsky Dep. II") at 16-18.) Finally, Dr. Krenitsky stated in no uncertain terms that he never revealed to anyone outside of GSK that he consumed valacyclovir.

> Q: Is it your testimony here today that you don't recall ever telling anyone outside the company that you were taking valacyclovir?
> A: Absolutely.

(Id. at 15.)

Dr. Nelson and Ms. Beauchamp provided similar testimony. Dr. Nelson unequivocally stated that "[n]o one outside of Burroughs Wellcome was aware that I was taking valacyclovir." (Nelson Dep. at 19.) When asked whether she discussed with

anyone outside of GSK that human volunteers were ingesting some of the compounds she synthesized, Ms. Beauchamp testified that "I don't recall doing that." (Beauchamp Dep. at 231.)

The factual record flatly contradicts Ranbaxy's intimation that Dr. Krenitsky informed people outside of GSK of valacyclovir and/or his use of it. Instead, the record establishes that the public did not have access to or knowledge of valacyclovir and the associated bioavailability data, and consequently buttresses a determination that the human ingestions of valacyclovir did not constitute "public use." See Allied Colloids, 64 F.3d at 1575 (supporting holding that reasonable jury could find no public use with observations that the customer did not observe testing, did not know composition of products being tested, and did not know test results).

3. Whether there was any confidentiality obligation imposed on persons who observed the use

It is undisputed that Ms. Beauchamp and her individual colleagues did not execute any separate, written confidentiality agreements among themselves. (GSK Fact Response at ¶ 5.) Written confidentiality agreements were, however, executed as part of GSK's employment agreements with Ms. Beauchamp, Dr. de Miranda, and Dr. Nelson. (GSK Fact Statement at ¶ 22.) This confidentiality obligation stated:

> You may not, during or after your employment, disclose for your benefit or to the detriment of the company any information concerning the business or affairs of the

> company which you may have acquired in the course of your employment.

(Id.) Although Dr. Krenitsky's employment contract could not be located, he stated that he had the same confidentiality obligation as that of his colleagues, and behaved accordingly (Ranbaxy Fact Response at ¶ 22; Krenitsky Dep. II at 109-11). In any event, Dr. Krenitsky's deposition testimony makes clear that he and other GSK employees understood the importance of maintaining confidentiality.

> [T]hat was just taken for granted that we didn't talk about our work outside the company. We are situated in the high tech area with other pharmaceutical companies, universities, et cetera, all around us; and it was -- there we were all very aware that our patentability would be ruined if we blabbed or we'd invite competition. . . . And we were very, very careful about confidentiality.

(Id. at 15.)

Ranbaxy attacks on multiple fronts the use of these confidentiality agreements to support a finding that confidentiality obligations were imposed on the valacyclovir users. As explained below, these challenges are either legally unsustainable or fail to raise a genuine dispute as to a material fact.

Ranbaxy first asserts that the confidentiality agreements existing between the three scientists and GSK are irrelevant to the public use determination and maintains that the appropriate inquiry is whether an obligation of confidentiality existed

between the inventor and the user. (Ranbaxy Br. at 11.) Ranbaxy argues that the absence of express confidentiality assurances between Ms. Beauchamp and the users mandates a finding that the uses were public. (Id. at 11-12.)

The case law does not support these contentions. The Federal Circuit has concluded on several occasions that an invention was not in public use despite the absence of an express confidentiality promise between the inventor and the user. These cases illustrate the proposition that written confidentiality agreements between the inventor and user are not necessary if the parties' relationship otherwise gives rise to an expectation of confidentiality. In TP Labs., Inc. v. Prof'l Positioners, Inc., 724 F.2d 965, 972 (Fed. Cir. 1984), the inventor's failure to obtain vows of secrecy from the patients on whom he used the claimed orthodontic device was insignificant because the inventor's control was "established inherently by the dentist-patient relationship of the parties." In reaching this conclusion and holding that no public use of the invention occurred, the court observed that "it is beyond reasonable probability that a patient would show the device to others." Id. Similarly, in Moleculon Research Corp. v. CBS, Inc., 793 F.2d 1261, 1265-66 (Fed. Cir. 1986), the nature of relationships between the inventor and those who observed the invention, including his roommate, school colleagues, and employer, gave

rise to a legitimately expected confidentiality even in the absence of an express agreement. Id. In addition to establishing that the circumstances surrounding a use may produce an implied confidentiality, these cases make clear that the absence of an express confidentiality agreement between the inventor and user does not ipso facto render a use "public" within the meaning of 35 U.S.C. 102(b). See Moleculon, 793 F.2d at 1266 ("[T]he presence or absence of such an agreement [of confidentiality with the inventor] is not determinative of the public use issue."); Allied Colloids, 64 F.3d at 1576 ("[T]he absence of such a promise [of confidentiality] does not make a use 'public' as a matter of law."). Instead, the surrounding circumstances must be examined. Id.

There can be no genuine dispute that the circumstances surrounding the development and testing of valacyclovir gave rise to an implied confidentiality between Ms. Beauchamp and her colleagues. The presence of confidentiality agreements between GSK and Dr. de Miranda, Dr. Nelson, and Dr. Krenitsky are relevant in that--contrary to Ranbaxy's argument--each scientist interpreted this agreement as precluding any discussion of Ms. Beauchamp's invention with persons outside of GSK. For example, Dr. Nelson testified as follows:

> Q: With respect to this data and the activities with valacyclovir, did you understand them to be confidential?
> A: Within the broad context of my, of my work agreement

> of keeping my scientific work with Burroughs Wellcome in confidentiality, yes.

(Nelson Dep. at 31-32.) Similarly, although Dr. Krenitsky could not locate his employment agreement with GSK, he testified that his general confidentiality agreement would cover specific knowledge regarding valacyclovir.

> Q: Did you have such an agreement regarding valacyclovir keeping the compound secret, did you have that kind of agreement with Burroughs Wellcome?
> A: No. Now wait a minute. Secret. I had a general agreement with Burroughs Wellcome not to disclose their science or their business; and so I had, in terms of my confidentiality agreement with them, yes, I did have an agreement that I shouldn't disclose what, about valacyclovir, but I didn't have a specific agreement on valacyclovir, I had a general agreement on all the technology and all the knowledge I had, okay?

(Krenitsky Dep. II at 85-86.) Dr. Krenitsky understood the testing of valacyclovir to be "secret."

> Q: And so it is also true you weren't required to keep your use of the drug secret according to any promise you made to her [Beauchamp]?
> (Objection.)
> A: Everything we did in the lab we kept secret and that was just ingrained in us. You know, we knew that you didn't talk about your lab work.
> . . . .
> Q: But do you recall having a specific requirement from Ms. Beauchamp that you would not be disclosing the fact that you were taking valacyclovir?
> (Objection.)
> A: No, but it would be somewhat ridiculous. We all knew that we didn't -- by disclosing you mean to outside people outside the company?
> Q: For this question, sure, outside the company.
> A: I mean we all knew. I mean that was just taken for granted we didn't talk about our work outside the company.

(Krenitsky Dep. II at 14-15.)

Ranbaxy's claim that the individuals who ingested the compound believed their uses were not secret is thus belied by the record, and its attempt to raise a genuine dispute regarding the presence of implied confidentiality between Ms. Beauchamp and the scientists who ingested the compound is unsustainable. Instead, the record conclusively reflects that, while no written confidentiality obligations existed specifically between the inventor and the users, each user interpreted his confidentiality agreement with GSK as prohibiting discussion of any aspect of the valacyclovir project outside the confines of GSK.[4] As such, Ms. Beauchamp, who herself signed such an agreement with GSK, (Rienzi Cert., Ex. J, Employment Agreement of Lilia Beauchamp), undeniably had a "legitimate expectation of privacy and confidentiality." Moleculon, 793 F.2d at 1265-66.

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[4] In support of its claim that "neither Nelson nor Krenitsky believed his use of valacyclovir was secret," Ranbaxy cites to deposition testimony that establishes only that the scientists did not consider their use of valacyclovir to be confidential within GSK. (Ranbaxy Reply Br. at 5.) Specifically, Ranbaxy relies upon Dr. Nelson's testimony that he understood the human testing was not secret "within our group," (Nelson Dep. at 24), as well as Dr. Krenitsky's testimony that the human testing "wasn't a deep dark secret. . . . And there were individuals that were around in the lab - the lab was crowded - that knew and they'd say, well, I'll help out if you need a volunteer" (Krenitsky Dep. II at 66). Read in the light most favorable to Ranbaxy, these testimonies at best establish that the scientists did not believe their use of valacyclovir to be confidential within GSK. Contrary to Ranbaxy's contention, they cannot reasonably be read to support the claim that the scientists did not consider their use of valacyclovir to be secret outside the company.

Ranbaxy's reliance on Minnesota Mining and Manufacturing Co. v. Appleton Papers, Inc., 35 F. Supp. 2d 1138 (D. Minn. 1999), and Netscape Communications Corp. v. Konrad, 295 F.3d 1315 (Fed. Cir. 2002), to support its position that the GSK confidentiality agreements are irrelevant is misplaced, as those decisions are materially distinguishable from this case. In Appleton, the inventors of a method for perforating carbonless paper manufactured and arranged for distribution of ten thousand sets of forms which embodied the invention throughout 3M, their employer company. Id. at 1147. The district court rejected 3M's proposition that the in-house distribution of an invention is nonpublic as a matter of law. Id. at 1148. The district court held that, despite the duty owed by 3M's employees not to disclose confidential business information, the dissemination of the ten thousand forms which embodied the patent triggered the public use bar. Id. at 1149, 1150, 1151. In stark contrast to this case, however, the district court emphasized that the employees who received the forms were not aware that the forms were made using a new process, that no evidence was put forth indicating that any employee would have understood the use and circulation of the form to be confidential, and that no company-wide policy existed regarding the use or circulation of the forms. Id. at 1149. In addition, thousands of sample forms were

distributed to an unknown number of employees. Id. The inventors exercised absolutely no control over who received the forms or how they were used, as evidenced by the fact that one employee frequently used the form to communicate with persons outside the company. Id. Turning to Netscape, Ranbaxy's interpretation of this case to mean that "to avoid operation of the public use bar, the inventor -- and not the assignee of the patent -- must secure confidentiality agreements with each of the users," is erroneous. (Ranbaxy Br. at 12.) Rather, after acknowledging that pledges of confidentiality are unnecessary in some circumstances, the Federal Circuit deemed the lack of such an agreement in that case significant because those to whom the invention was disclosed were not co-employees, but third parties who were never advised of any requirement of secrecy. Netscape, 295 F.3d at 1315, 1321. That those third parties were employed by the Department of Energy, which owned the patent rights to the invention, and were subject to the government's confidentiality requirements did not under the surrounding circumstances exonerate the inventor from his burden of protecting the confidentiality of his invention. Id. at 1322-23. This case differs significantly from Netscape. Ms. Beauchamp had explicit knowledge of GSK's confidentiality requirements and was entitled to rely on them in relinquishing her compound to her co-employees for the express purpose of assaying oral bioavailability, an area

within her colleagues' area of expertise. As shown above, these colleagues indisputably considered their uses of valacyclovir to be confidential.

Ranbaxy is correct that an obligation of confidentiality to a patent assignee or employer is not "controlling" on the issue of public use. See Netscape, 295 F.3d at 1323 ("[T]he limitation, restriction, or obligation of secrecy of others using the invention is owed to him [the inventor], not the persons or entity providing the funding."). This is because, as previously explained, no single factor is dispositive under the totality of the circumstances inquiry. See TP Labs., 724 F.2d at 971-972. Unlike in Netscape or Appleton, however, the obligations of confidentiality owed by Ms. Beauchamp, Dr. Nelson, Dr. de Miranda, and Dr. Krenitsky to their common employer and the interpretation of that obligation by each scientist as forbidding any discussion of valacyclovir outside the confines of GSK give rise to a reasonably expected implied confidentiality on the part of the inventor, Ms. Beauchamp. Indeed, requiring that an explicit pledge of confidentiality be executed directly between inventor and user to avoid the public use bar in the context of a large pharmaceutical corporation where the inventor and other scientists repeatedly collaborate with one another, play differing roles in drug development, and are obligated by their common employer to keep information learned in the course of

their employment confidential would be absurd and would hamstring drug development efforts.

Ranbaxy advances two additional challenges to our consideration of the GSK confidentiality agreements. First, Ranbaxy contends that the these confidentiality agreements "cannot operate to conceal uses of an unapproved drug." (Ranbaxy Br. at 11.) This argument is unavailing. Even setting aside the issue of the legality of the scientists' actions, whether or not the confidentiality agreements were or were not technically enforceable is irrelevant to the determination of whether a public use of valacyclovir occurred prior to the critical date. An "illegal" use of valacyclovir does not necessitate a finding that such use was "public" under 35 U.S.C. § 102(b). Instead, the Federal Circuit has adopted a pragmatic "totality of the circumstances" approach to assess whether or not a use was public under 35 U.S.C. § 102(b). See Netscape, 295 F.3d at 1320. This test is designed to determine the public or private nature of the challenged use, and not its technical legality. Assessing the secrecy surrounding the use is one aspect of that, and the existence of a confidentiality agreement between inventor and user just one piece of evidence illustrative of confidentiality. Second, Ranbaxy argues that the GSK confidentiality agreements did not encompass each scientist's self-ingestion of valacyclovir because the scientists considered those uses to be outside the

"scope of . . . employment." (Ranbaxy Reply Br. at 10.) This argument rests, however, on an untenable distortion of Dr. Nelson's and Dr. Krenitsky's testimony. Ranbaxy points to the following testimony of Dr. Krenitsky:

> Q: Even though you were taking valacyclovir at work, and then providing urine samples to Misty Burnette, is it still your position that you were taking valacyclovir outside of your job duties and responsibilities?
> (Objection.)
> A: Yes. It is my position.
> Q: So would you say you were taking it outside the course of your employment; is that a fair characterization?
> A: It was not part of my job description.

(Krenitsky Dep. II at 72.) Dr. Nelson stated that "[t]hese sorts of studies were not a requirement of my employment." (Nelson Dep. at 24.)

These testimonies, standing alone, can reasonably be read as supporting Ranbaxy's contention that the human uses of valacyclovir occurred outside the scope of employment. This reading becomes unreasonable, however, when considered in conjunction with testimony that Ranbaxy excluded. These statements make clear that each scientist, while not compelled to take valacyclovir, regarded human testing as part of the research program at GSK. Specifically, Dr. Krenitsky explained as follows:

> Q: So would you agree [consuming valacyclovir] was outside the course of your employment?
> (Objection.)
> A: I wasn't compelled to take it. I volunteered to

> take it, but it was certainly part of my scientific activities at Burroughs Wellcome. I don't know what the distinction should be here but --

(Krenitsky Dep. II at 72-73.) Immediately prior to the testimony cited by Ranbaxy, Dr. Nelson testified similarly:

> Q: Would you say that your taking or consuming valacyclovir in 1987, that was something that you did as part of an employee of Burroughs Wellcome or something you did independently?
> (Objection.)
> A: I participated in these studies on a volunteer basis.
> Q: So as an individual?
> (Objection.)
> A: These studies were part of our development strategy for drug candidates, and I voluntarily participated.

(Nelson Dep. at 23.) He also stated that "[t]hese sorts of studies were part of our experimental strategy to understand the bioavailability and metabolism of interesting candidates." (Id. at 14.)

These testimonies, considered in their totality, establish that, while not a requirement of employment at GSK, the consumption of valacyclovir was done in furtherance of GSK's drug development programs. Ranbaxy has not succeeded in raising a genuine dispute regarding whether each scientist's self-ingestion occurred outside the "course of . . . employment." (Rienzi Cert., Ex. I, Employment Agreements of Lilia Beauchamp, Paulo de Miranda and Donald Nelson.)

Ranbaxy, in addition, and perhaps more importantly, misapprehends the purpose for which these employment agreements

are offered. Whether these contracts are legally enforceable is not at stake; rather, in this context, they only serve as evidence that the human testing at GSK was confidential and not a "public use" within the meaning of 35 U.S.C. § 102(b). Indeed, even the complete absence of a confidentiality agreement cannot create a public use when the totality of the circumstances dictate otherwise. See, e.g., Allied Colloids, 64 F.3d at 1575-76.

In conclusion, we find that the implied confidentiality present between Ms. Beauchamp and those scientists who ingested valacyclovir further indicates that no public use of the invention occurred.

4. Whether persons other than the inventor performed the testing

It is uncontested that the self-administration of valacyclovir in this case was done by Drs. Krenitsky, de Miranda, and Nelson, and not by the inventor, Ms. Beauchamp. (Ranbaxy Fact Statement at ¶¶ 3, 4.) Ranbaxy maintains that Ms. Beauchamp was not aware that these human uses occurred until after they were completed, and contends that she therefore retained no control over her invention.[5] (Ranbaxy Br. at 8.) In support of

[5] Ranbaxy makes the leap that a lack of control on the part of the inventor renders the contested claims invalid as a matter of law. (Ranbaxy Reply Br. at 4.) A finding that Ms. Beauchamp exercised no control over the use of her invention by her colleagues would be a factor weighing in favor of holding that her invention was in public use. As explained above, however, no

this assertion, Ranbaxy highlights the following testimony of Ms. Beauchamp:

> Q: My question was: Were you used to seeing human volunteers test out compounds --
> A: I didn't see them, you know, I wasn't used to anybody participating in this work. I was told later on that it had been done. So when you say I'm used to, for all I know, it wasn't done a lot, it was done sometimes, I didn't know. It had nothing to do with me.

(Beauchamp Dep. at 229-30.) In addition, Ranbaxy relies upon the following testimony of Dr. Krenitsky as confirmation that Ms. Beauchamp retained no control over her invention:

> Q: Were you instructed by Lilia Beauchamp to take the drug?
> A: Absolutely not.
> . . . .
> Q: She was not controlling your taking valacyclovir; is that correct?
> (Objection.)
> Krenitsky: No. That was my personal choice.

(Krenitsky Dep. II at 10, 13.) Finally, Ranbaxy points to Dr. Nelson's statement that he did not recall Ms. Beauchamp asking him to take valacyclovir, and the fact that Dr. Nelson was not part of the valacyclovir development team, as further evidence of Ms. Beauchamp's lack of control. (Nelson Dep. at 18, 13.)

Reading the evidence and construing all reasonable inferences in favor of Ranbaxy, Ms. Beauchamp did not provide her invention to Dr. de Miranda for the purpose or with the

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single factor is controlling on the public use determination. See supra Part II.A.iii.

expectation of human ingestion and had no knowledge that Drs. Krenitsky, Nelson, and de Miranda orally consumed the compound until after those consumptions occurred. However, such findings do not, in light of the surrounding circumstances, warrant the conclusion that she did not have appropriate supervision or control over valacyclovir.

At the time these tests occurred, Dr. Krenitsky served as Head of GSK's Experimental Therapy Department, and Dr. de Miranda and Dr. Nelson were both Group Leaders in the Experimental Therapy Department. (Krenitsky Dep. II at 12-13; Krzeminski Decl., Ex. K, Dep. of Thymista Burnette at 110-111; Nelson Dep. at 10.) Ms. Beauchamp, a chemist in GSK's Organic Chemistry Department, provided samples of the compounds that she synthesized, including valacyclovir, to Dr. de Miranda. (GSK Fact Statement at ¶ 4; Ranbaxy Fact Response at ¶ 20.) In doing so, Ms. Beauchamp sought oral bioavailability data. (Beauchamp Dep. at 90, 238-239.) Dr. Krenitsky, who was also involved in the oral bioavailability analyses of amino acid ester prodrugs of acyclovir, understood this to be Ms. Beauchamp's purpose as well. (Ranbaxy Fact Response at ¶ 5.)

> Q: When Ms. Beauchamp provided prodrugs she had made to the experimental therapy department, do you know what her purpose was in doing that?
> A: Oh, she clearly intended for them to see if they would be good prodrugs for acyclovir. . . .
> Q: Was she aware that tests would be conducted for oral bioavailability by the experimental therapy department?
> A: Absolutely. She was part of the team of Paulo,

> myself and Lil that, you know, we strategized together and she was certainly part of the plan and certainly therefore aware of it.

(Krenitsky Dep. II at 111.)

Ms. Beauchamp, an organic chemist, did not herself conduct any oral bioavailability testing. (Ranbaxy Fact Response at ¶ 9.) Instead, she relied upon the expertise of Dr. de Miranda and others in the Experimental Therapy Department. (Id.; Beauchamp Dep. at 72-73; Krenitsky Dep. II at 13.) As such, the protocols for oral bioavailability testing were devised by those in the Experimental Therapy Department. According to Dr. Krenitsky:

> Q: Who went about creating this system of collecting the urine at these intervals? Whose idea was it to have this sort of a protocol?
> (Objection.)
> A: I can't remember specifically who but it was probably combination [sic] of Paulo and myself.
> Q: Do you know whether Lilia Beauchamp had any input into this?
> A: Well, she doesn't have a background in pharmacokinetics and she deferred to our expertise.

(Krenitsky Dep. II at 62-63.)

Although Ms. Beauchamp did not direct the specific methods of the Experimental Therapy Department's bioavailability testing, she was provided with and relied upon the resulting data. (Ranbaxy Fact Response at ¶ 9; Beauchamp Dep. at 90; Krenitsky Dep. II at 14.) Ms. Beauchamp testified that she relied on both the human and rat data to determine what additional compounds to create.

> Q: You were responsible for that. And was the data from the bioavailability assessments important to you, particularly, or were you just responsible for conveying that?
> A: Well, it was very important. It would direct me to what direction to go in making additional compounds, if necessary. In other words, it was structure activity relationship in terms of metabolism.
> Q: And so you used the data, the urine recovery data to help guide you in which compounds to synthesize?
> A: Exactly.
> . . . .
> Q: And given that you were synthesizing compounds for possible use as pharmaceuticals, was the human urinary recovery data important to you?
> A: Yes.

(Beauchamp Dep. at 238-39.) It is undisputed that the human testing of valacyclovir was conducted for the purpose of garnering oral bioavailability data. (Ranbaxy Fact Response at ¶ 11.)

Ms. Beauchamp, although she did not expressly direct scientists of the Experimental Therapy Department to ingest valacyclovir, did supply them with samples of the compound for the purpose of obtaining oral bioavailability data. She was furnished with both human and rat bioavailability results, and she relied upon those results.

It is not reasonable, in light of these facts, to infer that Ms. Beauchamp lost control over her invention merely because her colleagues in the Experimental Therapy Department devised the proper protocols and conducted the bioavailability testing using a method not known to her. Instead, this reflects her lack of expertise in the area. Indeed, it would not be reasonable to

expect Ms. Beauchamp, an organic chemist, to direct in detail the manner in which the Experimental Therapy group were to conduct bioavailability testing--a group upon whose expertise in this area she specifically relied. Her failure to possess knowledge of the details of testing done by her co-workers does not render the testing activities "public." Ranbaxy overlooks Ms. Beauchamp's undisputed expectation that in-house testing of the oral bioavailability properties of her invention would occur, and that the testing undertaken, including the human testing, was done by her colleagues in furtherance of this expectation. Adopting Ranbaxy's argument would require the Court to ignore the reality of drug development in pharmaceutical corporations.

The caselaw comports with this determination. In support of its holding that no public use of an orthodontic invention occurred, the Federal Circuit stated in TP Labs., Inc. v. Prof'l Positioners, Inc., 724 F.2d 965 (Fed. Cir. 1984), that "the routine checking of patients [using the invention] by one of the other K & R orthodontists [inventor's colleagues] does not indicate the inventor's lack of control or abandonment to the public." Id. at 972. Similarly, an inventor's absence from the testing of his invention by the patent owner's employees was insignificant in Allied Colloids, where the Federal Circuit vacated a grant of judgment as a matter of law of an invalidating public use. 64 F.3d at 1575, 1577. In that case, there was no

evidence of any written confidentiality agreements either between inventor and patent owner's employees or patent owner and customer. Id. at 1576. The cases do not support the assertion that when an inventor relies on a co-employee to test the invention for a specific property, the inventor will be deemed to have lost control unless she is aware of every detail of that testing.

Further buttressing this Court's finding that Ms. Beauchamp retained control over her invention is that no breach of confidentiality in fact occurred. See Allied Colloids, 64 F.3d at 1576 ("Although a written promise of confidentiality is a factor to be considered in appropriate circumstances, such as when persons other than the patentee conduct the experiments, the absence of such a promise does not . . . outweigh the undisputed fact that no information of a confidential nature was communicated to others." (internal citations omitted)). As detailed fully in the preceding section, Ranbaxy has failed to set forth a scintilla of evidence that any individual outside of GSK knew of the valacyclovir testing or associated bioavailability data.

Indeed, a finding that under these circumstances Ms. Beauchamp held absolutely no control over her invention would jeopardize the validity of many patented inventions developed by scientists working in collaborative environments. This is not a

case where the inventor placed her invention in the public domain and relinquished control. Although Ms. Beauchamp did not perform the testing on her invention, the record establishes that she retained adequate "control" over its use.

5. Number of tests, length of test period, and whether the inventor received payment for the testing

The last three factors pertinent to determining whether a public use occurred--the number of tests, the length of the test period in relation to tests of similar devices, and whether the inventor received payment for the testing--all favor holding that no public uses of valacyclovir occurred. Only four purportedly invalidating uses took place: two by Dr. Krenitsky and one each by Drs. de Miranda and Nelson. (Ranbaxy Fact Statement at ¶¶ 3, 4); See TP Labs., 724 F.2d at 972 (observing that "use on three patients is not an obviously excessive number"). These uses all occurred within six months after the compound was first synthesized by Ms. Beauchamp. (Ranbaxy Fact Statement at ¶¶ 2-4.) There is no evidence that Ms. Beauchamp received any payment for the testing, which was done by her co-employees for the purpose of obtaining oral bioavailability data. (GSK Fact Statement at ¶ 11; Ranbaxy Fact Response at ¶ 11); See Allied Colloids, 64 F.3d at 1576 ("[T]he absence of payment supports the inference that the tests were for the benefit of the patentee, and thus contravenes the inference of public use for or by the potential customer.").

B. The totality of the circumstances compels the conclusion that no public use of the invention occurred

"[A] decision on whether there has been a 'public use' can only be made upon consideration of the surrounding circumstances." TP Labs., 724 F.2d at 972; See Allied Colloids, 64 F.3d at 1576 ("All of the circumstances must be considered, to ascertain whether on the entirety of the evidence it has been proved that the patented invention was publicly used.").

The above examination of the totality of the circumstances surrounding the development and use of valacyclovir makes apparent that the contested uses of valacyclovir did not constitute "public use" within the meaning of 35 U.S.C. § 102(b). In sum, there is no dispute that the challenged human ingestions of valacyclovir all occurred within the confines of GSK by GSK scientists working for the commonly understood purpose of assessing the chemical compound's oral bioavailability. This area of science was not within Ms. Beauchamp's expertise. In addition, it is beyond dispute that Ms. Beauchamp, a fellow GSK employee, provided these scientists with her invention for the limited, restricted purpose of obtaining oral bioavailability data, and that the scientists complied with that directive, albeit using methods not contemplated by the inventor. Furthermore, no genuine dispute exists that these scientists, all bound by confidentiality agreements with their common employer, understood that their use of valacyclovir and the data resulting

therefrom were to be kept confidential, and that they did in fact keep it confidential. Ms. Beauchamp herself owed the same duty of confidentiality to GSK. This is not a case where an inventor "having made his device, gives or sells it to another, to be used by the donee or vendee, without limitation or restriction, or injunction of secrecy, and it is so used." Egbert v. Lippman, 104 U.S. 333, 336 (1881). These facts compel the legal conclusion that no public use of valacyclovir occurred prior to the critical date.[6]

C. Policy

The determination that no public use of valacyclovir occurred as a matter of law offends none of the policies that underlie the public use bar. Indeed, three of the four policies are not even implicated. First, valacyclovir was never placed in the public domain prior to the critical date. Second, no commercial activity occurred prior to the critical date. Finally, "favoring prompt and widespread disclosure of inventions" is not violated under these circumstances because the compound was first synthesized in February 1987, and a United States patent application filed in August 1988.

[6] This holding obviates the need to discuss applicability of the experimental use negation.

CONCLUSION

The evidence material to the public use inquiry under 35 U.S.C. § 102(b) is not genuinely disputed and, drawing all justifiable inferences in Ranbaxy's favor, compels the conclusion that the human consumptions of valacyclovir were not public uses under 35 U.S.C. § 102(b).[7] As a matter of law, Ranbaxy cannot carry its burden in proving by clear and convincing evidence that the inventor made a public use of the invention within the meaning of 35 U.S.C. § 102(b). Accordingly, we will grant GSK's cross-motion for partial summary judgment of no patent invalidity due to public use. A separate order will follow.

s/ Mary L. Cooper
MARY L. COOPER
United States District Judge

[7] Ranbaxy's allegations that the human intake of valacyclovir by GSK scientists violated the Federal Food Drug and Cosmetic Act laws are irrelevant to proper disposition of this matter, which involves application of the patent laws of Title 35 of the United States Code. We have not been assigned the responsibility of adjudicating FFDCA violations in the course of resolving patent disputes. Indeed, the Federal Circuit has cautioned against entertaining such inquiries. See, e.g., Mylan Pharms., Inc. v. Thompson, 268 F.3d 1323, 1329-30 (Fed. Cir. 2001); Regents of the Univ. of Cal. v. Eli Lilly & Co., 119 F.3d 1559, 1569-71 (Fed. Cir. 1997).